DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of the Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 4, 1999, 8 a.m. to 5 p.m.

Location: Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Contact Person: Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180 or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 4, 1999, in the morning session, the committee will discuss issues for new barrier contraceptive devices such as premarket study design, prescription versus over-the-counter availability, and premarket versus postmarket studies. The following current guidance documents are available as references: (1) ''Testing Guidance for Male Condoms Made from New Material,'' (2) ''Guidance for Industry: Uniform Contraceptive Labeling,'' and (3) ''Premarket

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Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases.'' Single copies of these guidance documents are available to the public by contacting the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or by faxing your request to 301–443–8818 and requesting the document by shelf numbers 455, 1251, and 384, respectively. They are also available on the Internet using the World Wide Web at http://www.fda.gov/cdrh/ode/oderp455.html, http://www.fda.gov/cdrh/ode/contrlab.html, and http://www.fda.gov/cdrh/ode/384.pdf.

In the afternoon session, the committee will discuss clinical study requirements for new nonextirpative methods of treating uterine fibroids.

Procedure: On October 4, 1999, from 9 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 27, 1999. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 1:30 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before September 27, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 4, 1999, from 8 a.m. to 9 a.m., the meeting will be closed to permit the committee to hear and review trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the October 4, 1999, Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and

qualified members of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-

day public notice. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 17, 1999

Linda A. Suydam
Senior Associate Commissioner

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